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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------|----------------------|----------------------|------------------|
| 09/898,975 | 07/03/2001 | Eric J. Schmitt | 6286.N | 9955 |
| 7 | 590 06/30/2003 | | | |
| Andrew M. Solomon Pharmacia & Upjohn Company Global Intellectual Property 301 Henrietta Street Kalamazoo, MI 49001 | | | EXAMINER | |
| | | | LANKFORD JR, LEON B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |
| | | | DATE MAN ED 0/100000 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|---|-------------------------|--|--|--|--|--|
| - | Applicati n N . | Applicant(s) | | | | |
| | 09/898,975 | SCHMITT ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | L Blaine Lankford | 1651 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the cerrespondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | |
| 1) Responsive to communication(s) filed on | | | | | | |
| 2a)☐ This action is FINAL . 2b)⊠ Thi | s action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims 4)⊠ Claim(s) 1-11 is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-11</u> is/are rejected. | | | | | | |
| 7)☐ Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal F | (PTO-413) Paper No(s) Patent Application (PTO-152) | | | | |
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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claims are confusing in that they call for the administration of semen with a prostaglandin (and compositions of semen and a prostaglandin) yet semen contains prostaglandins (particularly $\alpha 2$). It would appear that applicant's invention is intended to be different from what is claimed. As such, claim 1 does not make it clear what the reduction is in comparison to.

Further, claim 4 is confusing- it is unclear what level of improvement is being claimed. Also as semen contains prostaglandins, it is unclear what the reference for the comparison/improvement is.

Claim 8 is confusing in that tit is unclear if any antibiotic administration is intended or it the antibiotic is to be in the semen sample.

Please note that the language of a claim must make it clear what subject matter the claim encompasses to adequately delineate its "metes and bounds". See, e.g., the following decisions: In re Hammack, 427 F 2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); In re Venezia 530 F 2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); In re Goffe, 526 F 2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); In re Watson, 517 F 2d. 465, 477, 186

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USPQ 11, 20 (CCPA 1975); In re Knowlton 481 F 2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-9 & 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Thistlewaite et al (5402240) or Wiesman(5983661).

Thistlewaite (see e.g. Col 1) & Wiesman (see e.g. Col 1) teach inseminating animals with a composition which comprises semen, an extender, a prostaglandin and an antibiotic. The references anticipate the claim subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the

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various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thistlewaite et al (5402240) or Wiesman(5983661) in view of Bowler et al(400421) and Hayashi et al(3953495).

Thistlewaite (see e.g. Col 1) & Wiesman (see e.g. Col 1) teach inseminating animals with a composition which comprises semen, an extender, a prostaglandin and an antibiotic. As the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition and are result effective variables, they would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by those references. That also extends to the selection of antibiotic as the references (particularly Weisman) teach a multitude of useful antibiotics and the selection of a suitable antibiotic would have been well within the purview of one of ordinary skill in the art.

Certain embodiments of applicant's invention may not be suggested by

Thistlewaite and Weisman however the administration of prostaglandins to a female

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mammal to improve impregnation is notoriously old and well known in the art as taught by Hayashi and Bowler (Cols 1-2 in both references).

Furthermore, it would have been obvious at the time the invention was made to practice the invention of the references with other mammals given that the uterine reaction to prostaglandins is well known in mammals.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to L Blaine Lankford whose telephone number is 308-2455. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

L Blaine Lankford

Pramary Examiner

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LBL

June 28, 2003